

REMARKS

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims.

Status of the Claims

In the present Reply, claim 15 has been amended and claims 22-24 have been added. Also, claims 11-14 and 16-20 were previously canceled, and claim 21 is canceled herein without prejudice or disclaimer of the subject matter contained therein. Further, claims 1-10 stand allowed (see paragraph 6 of the Office Action). Thus, claims 1-10, 15 and 22-24 are pending in the present application.

No new matter has been added by way of the amendment and new claims, because each amendment and new claim is supported by the present specification. For example, the amendment to claim 15 is merely editorial in nature and has support in the present specification at pages 21+. New claim 22 drawn to a preferred embodiment of the present invention has been added for consideration. Support for this new claim is found at least at page 8 of the present specification. Also, new claim 23 has support in the specification at pages 8 and 21+. Finally, new claim 24 is similar in scope to claim 1, except R⁵ is not "an optionally substituted carboxyl group." Thus, no new matter has been added.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues Under 35 U.S.C. § 112, First Paragraph

Claims 15 and 21 stand rejected under 35 U.S.C. § 112, first paragraph, for asserted lack of written description (see paragraph 1 of the Office Action). Applicants respectfully traverse, and reconsideration and withdrawal of this rejection are respectfully requested.

First, Applicants submit that the rejection of claim 21 is rendered moot upon its cancellation herein.

Second, with regard to claim 15, Applicants respectfully traverse. Claim 15 is directed to a pharmaceutical composition comprising the compound of claim 1 in a pharmacologically effective amount. The Examiner states claim 15 is not enabled “with respect to the use of the compounds [that] has not been established as of yet” (see page 2 of the Office Action). The Examiner also cites M.P.E.P. § 2164.01(c) in the previous Office Action (dated September 27, 2004), which is entitled “How to Use the Claimed Invention.”

The cited M.P.E.P. § 2164.01(c) section also refers to in M.P.E.P. §§ 2107.01 and 2107.03. However, M.P.E.P. § 2107.01(III) refers to utility, wherein “Courts have repeatedly found that the mere identification of a pharmacological activity of a compound that is relevant to an asserted pharmacological use provides an ‘immediate benefit to the public’ and thus satisfies the utility requirement” (citing *Nelson v Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980)). That “mere identification” has been established, and thus this rejection has been overcome. Further, M.P.E.P. § 2107.03(I) also cites the *Nelson* case and states “Instead, all that is required is a reasonable correlation between the activity and the asserted use”. That reasonable correlation has been established, as further evidence by Applicants’ specification. Applicants

also refer the Examiner to M.P.E.P. § 2107.03(II) and the U.S. Patent cited in paragraph 6 of the Office Action.

Applicants also maintain that pending claim 15 is given the presumption of enablement and instantly precludes a rejection for enablement given how M.P.E.P. § 2164.01(c) states: “when a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use.” Applicants also maintain that since the previous paragraph of this part of the M.P.E.P. refers to a chimeric gene capable of being expressed in any cyanobacterium as an example of use for a compound or composition claim, that paragraph is not applicable here.

In addition, Applicants maintain that the burden has not shifted to Applicants since the Examiner has not established a *prima facie* case of nonenablement because the Examiner has not provided “acceptable evidence of nonenablement”. *See Utter v. Hiraga*, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988). Regarding pending claim 15, the Office Actions merely refer Applicants to a certain part of the M.P.E.P. without given acceptable evidence of nonenablement. More specifically:

- the outstanding Office Action merely recites one sentence out of the M.P.E.P. without further supporting scientific evidence;
- the Office Action of September 27, 2004 at page 2, lines 4-9 from the bottom also recites a sentence out of M.P.E.P. § 2164.01(c) without referring to scientific evidence; and
- the first Office Action of May 12, 2004 erroneously refers to how claim 15 is directed to a method.

Thus, withdrawal of the rejection of claim 15 is respectfully requested.

If these comments are not sufficient to overcome this rejection, **Applicants herein request clarification as to this issue and further request an Interview with the Examiner in an effort to advance prosecution.** Applicants note that Applicants' representative attempted to contact the Examiner before this Reply was filed in an attempt to clarify this issue.

Issues Under 35 U.S.C. § 112, Second Paragraph

Claim 21 stands rejected under 35 U.S.C. § 112, second paragraph, for a reason of indefiniteness (see paragraph 2 of the Office Action). Applicants respectfully request withdrawal of this rejection since this claim has been canceled.

Also, Applicants respectfully refer the Examiner to newly added claim 22 as presented herein. Given the remarks in the Office Action at page 3, last sentence, Applicants respectfully submit that this claim is in allowable form.

Paragraph 6 of the Office Action

Applicants appreciate the consideration given to the allowable claims. It is respectfully requested that the other pending claims be given the same status. Applicants also request consideration of the newly added claims, including new claim 24 since it is believed that at least claim 24 does not overlap in claimed scope with the cited U.S. Patent.

Conclusion

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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